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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-R-70, CMS-R-72, CMS-R-247, CMS-10151, CMS-10268, CMS-R-5, CMS-10615, and CMS-10062]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the Federal Register concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including any of the following subjects: (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by **[Insert date 60 days after the date of publication in the Federal Register]**:

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. Electronically. You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. By regular mail. You may mail written comments to the following address:

CMS, Office of Strategic Operations and Regulatory Affairs

Division of Regulations Development

Attention: Document Identifier/OMB Control Number _____

Room C4-26-05

7500 Security Boulevard

Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web Site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.
2. E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.
3. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786-1326.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see ADDRESSES).

- CMS-R-70 Information Collection Requirements in HSQ-110, Acquisition, Protection and Disclosure of Peer review Organization Information and Supporting Regulations
- CMS-R-72 Information Collection Requirements in 42 CFR 478.18, 478.34, 478.36, 478.42, QIO Reconsiderations and Appeals
- CMS-R-247 Expanded Coverage for Diabetes Outpatient Self-Management Training Services and Supporting Regulations
- CMS-10151 Data Collection for Medicare Beneficiaries Receiving Implantable Cardioverter-Defibrillators for Primary Prevention of Sudden Cardiac Death
- CMS-10268 Consolidated Renal Operations in a Web Enabled Network (CROWNWeb) Third-party Submission Authorization Form
- CMS-R-5 Physician Certification/Recertification in Skilled Nursing Facilities (SNFs) Manual Instructions
- CMS-10615 Healthy Indiana Program (HIP) 2.0 Beneficiaries Survey, Focus Groups, and Informational Interviews
- CMS-10062 Collection of Diagnostic Data from Medicare Advantage Organizations for Risk Adjusted Payments

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep

records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Information Collection Requirements in HSQ-110, Acquisition, Protection and Disclosure of Peer review Organization Information and Supporting Regulations; Use: The Peer Review Improvement Act of 1982 authorizes quality improvement organizations (QIOs), formally known as peer review organizations (PROs), to acquire information necessary to fulfill their duties and functions and places limits on disclosure of the information. The QIOs are required to provide notices to the affected parties when disclosing information about them. These requirements serve to protect the rights of the affected parties. The information provided in these notices is used by the patients, practitioners and providers to: obtain access to the data maintained and collected on them by the QIOs; add additional data or make changes to existing QIO data; and reflect in the QIO's record the reasons for the QIO's disagreeing with an individual's or provider's request for amendment. Form Number: CMS-R-70 (OMB control number: 0938-0426); Frequency: Reporting – On occasion; Affected Public: Business or other for-profits; Number of Respondents: 400; Total Annual Responses: 21,200; Total Annual Hours: 42,400. (For policy questions regarding this collection contact Winsome Higgins at 410-786-1835.)

2. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Information Collection Requirements in 42 CFR 478.18, 478.34, 478.36,

478.42, QIO Reconsiderations and Appeals; Use: In the event that a beneficiary, provider, physician, or other practitioner does not agree with the initial determination of a Quality Improvement Organization (QIO) or a QIO subcontractor, it is within that party's rights to request reconsideration. The information collection requirements 42 CFR 478.18, 478.34, 478.36, and 478.42, contain procedures for QIOs to use in reconsideration of initial determinations. The information requirements contained in these regulations are on QIOs to provide information to parties requesting the reconsideration. These parties will use the information as guidelines for appeal rights in instances where issues are actively being disputed. Form Number: CMS-R-72 (OMB control number: 0938-0443); Frequency: Reporting – On occasion; Affected Public: Individuals or Households and Business or other for-profit institutions; Number of Respondents: 2,590; Total Annual Responses: 5,228; Total Annual Hours: 2,822. (For policy questions regarding this collection contact Winsome Higgins at 410-786-1835.)

3. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Expanded Coverage for Diabetes Outpatient Self-Management Training Services and Supporting Regulations; Use: According to the National Health and Nutrition Examination Survey (NHANES), as many as 18.7 percent of Americans over age 65 are at risk for developing diabetes. The goals in the management of diabetes are to achieve normal metabolic control and reduce the risk of micro- and macro-vascular complications. Numerous epidemiologic and interventional studies point to the necessity of maintaining good glycemic control to reduce the risk of the complications of diabetes. Despite this knowledge, diabetes remains the leading cause of blindness, lower extremity amputations and kidney disease requiring dialysis. Diabetes and its complications are primary or secondary factors in an estimated 9 percent of hospitalizations (Aubert, RE, et al., Diabetes-related hospitalizations and hospital utilization. In: Diabetes in America. 2nd ed.

National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Disease, NIH, Pub. No 95-1468-1995: 553-570). Overall, beneficiaries with diabetes are hospitalized 1.5 times more often than beneficiaries without diabetes. HCFA-3002-F provided for uniform coverage of diabetes outpatient self-management training services. These services include educational and training services furnished to a beneficiary with diabetes by an entity approved to furnish the services. The physician or qualified non-physician practitioner treating the beneficiary's diabetes would certify that these services are needed as part of a comprehensive plan of care. This rule established the quality standards that an entity would be required to meet in order to participate in furnishing diabetes outpatient self-management training services. It set forth payment amounts that have been established in consultation with appropriate diabetes organizations. It implements section 4105 of the Balanced Budget Act of 1997. Form Number: CMS-R-247 (OMB control number: 0938-0818); Frequency: Recordkeeping and Reporting – Occasionally; Affected Public: Business or other for-profit institutions; Number of Respondents: 5327; Total Annual Responses: 63,924; Total Annual Hours: 197,542. (For policy questions regarding this collection contact Kristin Shifflett at 410-786-4133.)

4. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Data Collection for Medicare Beneficiaries Receiving Implantable Cardioverter-Defibrillators for Primary Prevention of Sudden Cardiac Death; Use: We provide coverage for implantable cardioverter-defibrillators (ICDs) for secondary prevention of sudden cardiac death based on extensive evidence showing that use of ICDs among patients with a certain set of physiologic conditions are effective. Accordingly, we consider coverage for ICDs reasonable and necessary under Section 1862 (a) (1) (A) of the Social Security Act. However, evidence for use of ICDs for primary prevention of sudden cardiac death is less compelling for certain patients.

To encourage responsible and appropriate use of ICDs, we issued a “Decision Memo for Implantable Defibrillators” on January 27, 2005, indicating that ICDs will be covered for primary prevention of sudden cardiac death if the beneficiary is enrolled in either an FDA-approved category B IDE clinical trial (42 CFR 405.201), a trial under the CMS Clinical Trial Policy (NCD Manual §310.1) or a qualifying prospective data collection system (either a practical clinical trial or prospective systematic data collection, which is sometimes referred to as a registry). Form Number: CMS-10151 (OMB control number: 0938-0967); Frequency: Occasionally; Affected Public: Business or other for-profits, Not-for-profit institutions; Number of Respondents: 1,702; Total Annual Responses: 82; Total Annual Hours: 139,356. (For policy questions regarding this collection contact JoAnna Baldwin at 410-786-7205.)

5. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Consolidated Renal Operations in a Web Enabled Network (CROWNWeb) Third-party Submission Authorization Form; Use: The Consolidated Renal Operations in a Web Enabled Network (CROWNWeb) Third-Party Submission Authorization form (CWTPSA) is to be completed by "Facility Administrators" (administrators of CMS-certified dialysis facilities) if they intend to authorize a third party (a business with which the facility is associated, or an independent vendor) to submit data to us to comply with the recently-revised Conditions for Coverage of dialysis facilities. The CROWNWeb system is the system used as the collection point of data necessary for entitlement of ESRD patients to Medicare benefits and for federal government monitoring and assessing of the quality and types of care provided to renal patients. The information collected through the CWTPSA form will allow us along with our contractors to receive data from authorized parties acting on behalf of CMS-certified dialysis facilities. Since February 2009, we have received 4,160 CWTPSA forms and anticipates that they will continue to receive no more than 400 new CWTPSA forms annually to address the creation of new facilities under the current participating “third party submitters.” Form Number: CMS-10268 (OMB control number: 0938-1052); Frequency: Occasionally;

Affected Public: Business or other for-profits and Not-for-profit institutions; Number of Respondents: 400; Total Annual Responses: 400; Total Annual Hours: 34. (For policy questions regarding this collection contact Victoria Schlining at 410-786-6878.)

6. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Physician Certification/Recertification in Skilled Nursing Facilities (SNFs) Manual Instructions; Use: Section 1814(a) of the Social Security Act (the Act) requires specific certifications in order for Medicare payments to be made for certain services. Before the enactment of the Omnibus Budget Reconciliation Act of 1989 (OBRA1989, Public Law 101-239), section 1814(a)(2) of the Act required that, in the case of post hospital extended care services, a physician certify that the services are or were required to be given because the individual needs or needed, on a daily basis, skilled nursing care (provided directly by or requiring the supervision of skilled nursing personnel) or other skilled rehabilitation services that, as a practical matter, can only be provided in a SNF on an inpatient basis. The physician certification requirements were included in the law to ensure that patients require a level of care that is covered by the Medicare program and because the physician is a key figure in determining the utilization of health services. Form Number: CMS-R-5 (OMB control number: 0938-0454); Frequency: Occasionally; Affected Public: Business or other for-profits and Not-for-profit institutions; Number of Respondents: 2,711,136; Total Annual Responses: 2,711,136; Total Annual Hours: 624,515. (For policy questions regarding this collection contact Kia Sidbury at 410-786-7816.)

7. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Healthy Indiana Program (HIP) 2.0 Beneficiaries Survey, Focus Groups, and Informational Interviews; Use: The collected information will be used to make decisions about the renewal of precedent-setting waivers of Medicaid policy that assure important beneficiary protections regarding coverage and access to care; e.g., the State of Indiana's non-emergency medical transportation waiver which

will end or will be extended by no later than December 1, 2016. To support CMS decision making, the collection's survey effort would provide more detailed information on the Healthy Indiana Program (HIP) 2.0 demonstration's beneficiary understanding and experiences (current and new enrollees as well as disenrollees/lockouts). Additional information on other key policies under the demonstration, such as the 60-day beneficiary lock-out period, is also included in this information collection request.

This request does not propose any new or revised information collection requirements or burden estimates outside of what is currently approved by OMB. Rather, it seeks to extend the collection's current expiration date of September 30, 2016 (approved under the emergency PRA process on March 21, 2016; see 81 FR 17460 dated March 29, 2016, and 81 FR 26798 dated May 4, 2016). Since the collection has already been subject to the public comment process for collection activities taking place through September 30, 2016, this "Extension of a currently approved collection" will only consider comments for activities taking place from October 1, 2016, through the end of the revised expiration date. The revised expiration date will be made available upon OMB approval at reginfo.gov. Form Number: CMS-10615 (OMB control number: 0938-1300); Frequency: Once; Affected Public: Individuals and households, Private sector (Business or other for-profits and Not-for-profits institutions), and State, Local, or Tribal Governments; Number of Respondents: 5,240; Total Annual Responses: 5,240; Total Annual Hours: 1,442. (For policy questions regarding this collection contact Teresa DeCaro at 202-384-6309.)

8. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Collection of Diagnostic Data from Medicare Advantage Organizations for Risk Adjusted Payments; Use: CMS requires hospital inpatient, hospital outpatient and physician diagnostic data from Medicare Advantage (MA) organizations to continue making payment under the risk adjustment methodology. CMS will use the data to make risk adjusted payment under Parts C and D. MA and MA-PD

plans will use the data to develop their Part C and D bids. As required by law, CMS also annually publishes the risk adjustment factors for plans and other interested entities in the Advance Notice of Methodological Changes for MA Payment Rates (every February) and the Announcement of Medicare Advantage Payment Rates (every April). Lastly, CMS issues monthly reports to each individual plan that contains the CMS Hierarchical Condition Category (HCC) and RxHCC models' output and the risk scores and reimbursements for each beneficiary that is enrolled in their plan. Form Number: CMS-10062 (OMB control number: 0938-0878); Frequency: Quarterly; Affected Public: Private sector (Business or other for profit and Not-for-profit institutions); Number of Respondents: 691; Total Annual Responses: 83,000,000; Total Annual Hours: 40,650. (For policy questions regarding this collection contact Michael P. Massimini at 410-786-1566.)

Dated: July 19, 2016

William N. Parham, III

Director, Paperwork Reduction Staff

Office of Strategic Operations and Regulatory Affairs

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